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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,644	11/26/2008	John P. Toscano III	61093(71699)	2708

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EXAMINER	
THOMAS, TIMOTHY P	
ART UNIT	**PAPER NUMBER**
1628	

NOTIFICATION DATE	DELIVERY MODE
06/16/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IP.Docketing@aporter.com

Office Action Summary	Application No.	Applicant(s)	
	10/587,644	TOSCANO ET AL.	
	Examiner	Art Unit	
	TIMOTHY P. THOMAS	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-52* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-7, 11, 42-44, 46, 49-52 (in part) and 8, drawn to a compound of formula I which contains formula II of claim 8.

Group II, claim(s) 1-7, 42-46 and 49-52 (in part), drawn to a compound of formula I which contains formula IV of claim 45.

Group III, claim(s) 1-7, 42-46 and 49-52 (in part), drawn to a compound of formula I which contains formula V of claim 45.

Group IV, claim(s) 1-7, 42-46 and 49-52 (in part), drawn to a compound of formula I which contains formula VI of claim 45.

Group V, claim(s) 1-7, 42-46 and 49-52 (in part), drawn to a compound of formula I which contains formula VII of claim 45.

Group VI, claim(s) 1-7, 9-16, 42-44, 46 and 49-52 (in part), drawn to a compound of formula I, excluding the compounds of Groups I-V, which contains a heterocycloalkyl, heterocyclyl or heteroaryl group.

Group VII, claim(s) 1-7, 9-16, 42-44, 46 and 49-52 (in part), drawn to a compound of formula I, excluding the compounds of Groups I-VI, which contains phenyl or formula (III) of claim 13 or 14.

Group VIII, claim(s) 1, 3-4, 11, 15-16, 42-44, 46 and 49-52 (in part), drawn to a compound of formula I, excluding the compounds of Groups I-VII, which contains a cycloalkyl, cyclyl or aryl group.

Group IX, claim(s) 1, 3-4, 11, 15-16, 42-44, 46 and 49-52 (in part), drawn to a compound of formula I, excluding the compounds of Groups I-VIII.

Group X, claim(s) 17 (in part), drawn to a pharmaceutical composition comprising a compound of Formula (I), without an additional therapeutic agent.

Group XI, claim(s) 17 (in part) and 18-20, drawn to a pharmaceutical composition comprising a compound of Formula (I) and an additional therapeutic agent.

Group XII, claim(s) 21-23, 25-30 and 34-41 (in part), drawn to a method of treating a subject suffering from or susceptible to a disease or disorder, comprising administering a compound of formula (I) without an additional therapeutic agent.

Group XIII, claim(s) 21-23, 25-30, 34-41 (in part) and 24, drawn to a method of treating a subject suffering from or susceptible to a disease or disorder, comprising administering a compound of formula (I) and an additional therapeutic agent.

Group XIV, claim(s) 31-32, drawn to a method of administering nitroxyl to a subject.

Group XV, claim(s) 33, drawn to a kit comprising a compound of Formula (I) and instructions.

Group XVI, claim(s) 47-48, drawn to a method of modulating a target.

Note: For any one of Groups X-XVI elected, applicant must also elect a corresponding group from Groups I-IX of the compound of Formula (I) present in the elected product or method group, X-XVI. This is a restriction requirement, not a species election.

2. The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups I-XVI is lacking a priori. There is no substantial structural feature of the compounds of formula (I), shared by the groups. Furthermore, even if the minimal component of the compounds of formula (I) were to be considered a technical feature shared by the groups, Fitzhugh et al. teaches the

compound N-(oxido-1-piperidinylimino)-hydroxylamine, RN 431080-01-2, which has the common core structure to the compounds of formula (I) (Caplus AN 2002:73572; 2002; IDS 3/26/2010 reference). Since Fitzhugh previously disclosed the technical feature, the technical feature lacks novelty.

Therefore, the technical feature linking the inventions of Groups I-XVI does not constitute a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the prior art. Accordingly Groups I-XVI are not so linked by the same or a corresponding special technical feature as to form a single inventive concept.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

For any one of Groups I-XVI elected, applicant is required to elect:

(i) a single disclosed compound of formula (I); elect a single compound within the scope of the elected group I-X, by specifying every substituent of formula (I) at a level that defines a single compound, or alternatively, elect a single compound disclosed in the specification that is within the scope of the elected group I-X.

(Note: applicant is cautioned that the election of a compound not specifically disclosed as filed will comprise New Matter);

and

If either one of Groups XII-XIII is elected, applicant is also required to elect:

(ii) a single disease specie from the diseases recited in claim 29

(iii) a single Marker determination specie; elect from:

(iii-a) a step of administration without determining the level of Marker (claim 21);

(iii-b) a step of administration and a step of determining the level of Marker (claim 34); if elected, applicant must further elect a single sequence specie: elect a specie from claim 35, 36 or 37;

and

If Group XVI is elected, applicant is also required to elect:

(iv) a single target specie; elect a single target specie from the species recited in claim 47 or 48.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise require all the limitations of an allowed generic claim. Currently, the following claim(s) are generic: all claims are generic for (i); claims 21-30 and 34-41 are generic for (ii); claims 21-30 and 41 are generic for (iii); claims 47-48 are generic for (iv)

The claims are deemed to correspond to the species listed above in the following manner:

(i) all claims

(ii) & (iii) claims 21-30 and 34-41

(iv) claims 47-48

4. REQUIREMENT FOR UNITY OF INVENTION

As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

WHEN CLAIMS ARE DIRECTED TO MULTIPLE CATEGORIES OF INVENTIONS

As provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).

5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does

not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention or species.

Should applicant traverse on the ground that the inventions have unity of invention (37 CFR 1.475(a)), applicant must provide reasons in support thereof. Applicant may submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. Where such evidence or admission is provided by applicant, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY P. THOMAS whose telephone number is (571) 272-8994. The examiner can normally be reached on Monday-Thursday 6:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax

phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Timothy P Thomas/
Examiner, Art Unit 1628